## REMARKS/ARGUMENTS

This Amendment is submitted in response to the Office Action mailed March 29, 2006. At that time claims 1-19 were pending in the application. In the Office Action, the Examiner indicated that claim 19 would be allowable if rewritten in independent form. However, the Examiner objected to the specification for informalities relating to the description of the formation of compound (93). The Examiner also rejected claims 1-18 under 35 U.S.C. §112, second paragraph for indefiniteness. Claims 14 and 17 were rejected under 35 U.S.C. §112, first paragraph for failing to satisfy the enablement requirement. Claims 1, 9 and 13 were rejected under 35 U.S.C. §102(a) as being anticipated by U.S. Patent No. 6,337,332 to Carpino et al. (hereinafter "Carpino"). Claims 1-3, 5-9 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,984,555 to Amschler et al. (hereinafter "Amschler"), U.S. Patent No. 4,710,502 to Wright, Jr. et al. (hereinafter "Wright, Jr."), PCT Application No. WO 01/23365 to Mederski et al. (hereinafter "Mederski"), and PCT Application No. WO 01/81346 to Sadhu et al. (hereinafter "Sadhu").

By this Amendment, the specification has been amended to better comply with 35 U.S.C. §112, second paragraph. Additionally, claims 1, 14, 15, 17 and 19 have been amended. Support for the amendments to claim 1 can be found, for example, in the disclosure of compounds (32), (33), (61), (62) and (105). Some of the other amendments to claims 1 and 15 were made to address typographical errors and for clarity. Support for the amendments to claims 14 and 17 can be found, for example, on page 7, line 16 to page 8, line 6 and on page 1, line 32 to page 3, line 6. Support for amendments to claim 19 can be found, for example, in the disclosure of compound (31). Accordingly, claims 1-19 are presented for reconsideration by the Examiner.

## ALLOWABLE SUBJECT MATTER

The Examiner indicated that claim 19 would be allowable if rewritten in independent form. *See* Office Action, page 11. By this paper, claim 19 has been amended to be in independent form. Allowance of this claim is respectfully requested.

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**OBJECTION TO THE SPECIFICATION**

The Examiner objected to the specification because the process described in preparing compound (93) requires correction. *See* Office Action, page 2. By this paper, the specification has been corrected to address this objection.

**REJECTION OF CLAIMS 1-18 UNDER 35 U.S.C. §112, ¶2**

The Examiner rejected claims 1-18 under 35 U.S.C. §112, second paragraph, as being indefinite. *See* Office Action, page 3. The claims and the specification have been amended to address these issues.

First, the Examiner indicated that the definition of $R^5$ is unclear, *i.e.*, it is not apparent which group the list of substituents modifies. By this paper, claim 1 was amended to recite that "wherein the thienyl, styryl, pyridyl and phenyl group is optionally substituted..." Consequently, the list of substituents applies to the thienyl, styryl, pyridyl and phenyl group.

Second, the Examiner indicated that the claim language reciting $R^7$ as "an aromatic group" is indefinite because the definition for "aryl" provided in the specification is unclear. By this paper, the definition of "aryl" has been amended to clarify that the aryl group may be a monocyclic or polycyclic system and that aryl applies to both carbocyclic aryl and heterocyclic aryl. Furthermore, by this paper, claim 1 has been amended to recite that "$R^7$ is chosen from a pyridyl and a phenyl group...." Accordingly, the rejection under §112, second paragraph should be withdrawn.

Third, the Examiner rejected claim 14 because it "reads on diseases not yet known to be caused by or affected by such an action, or in way [s] not yet understood." Section 112, second paragraph requires that "the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the art." MPEP §2171. Applicants respectfully emphasize that a later development in the art does not render claims unpatentable under §112. *See, e.g., Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003) (§112 "focuses on a comparison between the specification and the invention referenced by the terms of the claim—not comparison between how the product was made as disclosed in the patent and future developments of this process that might alter or even improve how the same product is made.").

By this paper, claim 14 has been amended to recite "A method of treating a disease or disorder characterized by abnormal bone or mineral homeostasis *which is treatable by increasing serum parathyroid hormone levels*...." The specification provides sufficient support to demonstrate that the compound of claim 1 may be used to increase serum PTH levels. *See, e.g.*, page 7, line 16 to page 8, line 6. The specification also establishes that there are many diseases or disorders that may be treatable by increasing serum PTH levels. *See, e.g.*, page 62, lines 22-26. Consequently, one of ordinary skill in the art would readily appreciate the metes and bounds of claim 14, and therefore, claim 14 is definite as required by §112.

One example of utility of the invention is that the compound of claim 1 increases serum PTH levels, which is useful in treating diseases associated with abnormal bone or mineral homeostasis. The Examiner is essentially arguing that the claim is indefinite because not all possible or potential utilities (*i.e.*, disease states) are disclosed. Just because all possible utilities of the invention have not been identified (because some may not yet be known), does not mean that the claim is invalid for indefiniteness.

In the present case, the determination of definiteness under §112 must be made by comparison of what is recited in the claims and what is taught in the specification, not what may or may not be invented or discovered in the future. Since the specification teaches how to increase serum PTH levels by administering the compound of claim 1, and claim 14 recites a method of treating a disease or disorder "which is treatable by increasing serum parathyroid hormone levels," then the specification provides sufficient support for claim 14. The breadth of the claim is easily appreciated by one with ordinary skill in the art since it requires treating diseases or disorders that are treatable by increasing serum PTH levels.

Fourth, the Examiner rejected claim 17 because it also "reads on diseases not yet known...[or] not yet understood." However, the claim recites a method of increasing serum parathyroid hormone by administering an effective amount of the compound of claim 1. A catalog of diseases and disorders that may be treated by increasing PTH levels in not required to meet the requirements of §112, second paragraph. The claim recites a method of increasing serum PTH levels. As discussed above, one example of utility of the invention is that the increase in PTH levels is useful in treating diseases associated with abnormal bone or mineral

homeostasis. Just because all possible utilities of the invention have not been identified does not mean that the claim is invalid for indefiniteness. Withdrawal of this rejection is respectfully requested.

**REJECTION OF CLAIMS 14 and 17 UNDER 35 U.S.C. §112, ¶1**

The Examiner rejected claims 14 and 17 under 35 U.S.C. §112, first paragraph for not meeting the enablement requirement. *See* Office Action, page 4. Applicants respectfully traverse this rejection.

As a result of this paper, claims 14 and 17 both recite "increasing serum parathyroid hormone levels." The specification provides a detailed account of how to increase serum PTH levels *in vivo* using the claimed invention. *See* page 7, line 16 to page 8, line 6 and Figures 1 and 2. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988); MPEP §2164.01. The Examiner has the burden to establish a reasonable basis why the enablement requirement is not met by applying the *Wands* factors. *See* MPEP §2164.04.

In the Examiner's analysis of the *Wands* factors, the Examiner suggests that the specification only describes *in vitro* assay for detecting an increase of serum PTH. *See* Office Action, page 6. However, as described in the specification, an *in vivo* study of the administration of compound (17) showed a rapid, transient dose-related increase in plasma PTH levels (*see* Figure 2). This disclosure provides a significant amount of "direction and guidance" (*In re Wands*) to practice the claimed invention, as amended. Since claims 14 and 17 are directed to increasing serum PTH levels, and the specification provides a detailed account of how to increase serum PTH levels *in vivo* using compounds of the claimed invention, the skilled clinician would not have to engage in undue experimentation to use the claimed compounds in the methods recited in claims 14 and 17. Consequently, the rejected claims comply with §112, first paragraph. Withdrawal of this rejection is respectfully requested.

**REJECTION OF CLAIMS 1, 9 and 13 UNDER 35 U.S.C. §102(a)**

Claims 1, 9 and 13 were rejected under 35 U.S.C. 102(a) as being anticipated by Carpino. *See* Office Action, page 8. Applicants respectfully traverse this rejection.

It is well settled that a claim is anticipated under 35 U.S.C. § 102 only if "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." MPEP §2131, citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

As a result of this paper, claim 1 does not include hydrogen as a possible $R^6$ group, as is taught by Carpino. Consequently, claim 1, as well as claims 9 and 13 which depend on claim 1, are not anticipated because each and every element of claim 1 is not disclosed by Carpino. Withdrawal of this rejection is respectfully requested.

**REJECTION OF CLAIMS 1-3, 5-9 and 13 UNDER 35 U.S.C. §102(b)**

A. Rejection of claims 1, 2 and 5-9 in light of Amschler

Claims 1, 2 and 5-9 were rejected under 35 U.S.C. §102(b) as being anticipated by Amschler. *See* Office Action, page 9. Applicants respectfully traverse this rejection. As discussed above, a claim is anticipated under §102 only if it discloses each and every claim element. MPEP §2131. As a result of this paper, claim 1 does not include hydrogen as a possible $R^6$ group or lower alkyl as a possible $R^5$ group, as is taught by Amschler. Claims 1, 2 and 5-9 are, therefore, not anticipated because Amschler does not disclose each and every element of claim 1. Withdrawal of this rejection is respectfully requested.

B. Rejection of claims 1-3, 5-9 and 13 in light of Wright, Jr.

Claims 1-3, 5-9 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by Wright, Jr. *See* Office Action, page 9. Applicants respectfully traverse this rejection. As a result of this paper, claim 1 does not include imidazolyl as a possible $R^7$ group. Instead, $R^7$ may be a pyridyl or a phenyl group. Support for this claim limitation may be found, for example, with compounds 2-60 (for phenyl) and compounds 61-62 (for pyridyl). Consequently, claims 1-

3, 5-9 and 13 are not anticipated because Wright, Jr. does not disclose each and every element of claim 1. Withdrawal of this rejection is respectfully requested.

C. Rejection of Claims 1-3, 5-9 and 13 in light of Mederski

Claims 1-3, 5-9 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by Mederski. *See* Office Action, page 10. Applicants respectfully traverse this rejection. As a result of this paper, claim 1 recites that $R^7$ is a phenyl or pyridyl group optionally substituted with *unsubstituted* lower alkyl. Support for this amendment can be found, for example, in the disclosure of compounds (32) and (33). Mederski, however, discloses an amino-substituted methyl group on a phenyl ring at the 3 position of the quinazolinone backbone. Mederski does not disclose an unsubstituted alkyl at this position. Claims 1-3, 5-9 and 13 are, therefore, not anticipated because Mederski does not disclose each and every element of claim 1. Withdrawal of this rejection is respectfully requested.

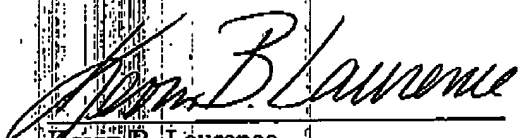
D. Rejection of Claims 1-3 and 6-9 in light of Sadhu

Claims 1-3 and 6-9 were rejected under 35 U.S.C. §102(b) as being anticipated by Sadhu. *See* Office Action, page 10. Applicants respectfully traverse this rejection. As a result of this paper, claim 1 does not include alkyl or lower alkyl as a possible $R^5$ group. Instead, according to claim 1, $R^5$ is hydrogen or an optionally substituted thienyl, styryl, pyridyl or phenyl group. Consequently, claims 1-3 and 6-9 are not anticipated because Sadhu does not disclose each and every element of claim1. Withdrawal of this rejection is respectfully requested.

## CONCLUSION

Applicants respectfully assert that claims 1-19 are patentably distinct from the cited references, and request that a timely Notice of Allowance be issued in this case. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Respectfully submitted,



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